Improvements Relating To An Inhalation Device

The present invention relates to a device for the protection of a dose of medicament in an inhalation device for use in the administration of medicament to a patient.

The use of inhalation devices in the administration of medicaments, for example in bronchodilation therapy, is well known. Such devices generally comprise a body or housing within which a medicament container is located. A mouthpiece (or nozzle) is typically provided, wherein 'in use' the mouthpiece communicates with the medicament container to allow passage of medicament from the source to the mouthpiece and thence, to the patient.

In a typical dispensing operation the body of the device is held by the patient and the mouthpiece (or nozzle) of the inhalation device is placed in the mouth (or nose) of the patient. The patient inhales, thereby causing transfer of medicament from the medicament container to the interior of the body of the patient.

Many inhalers are known where the medicament is stored in a pocket, which is sealed for the purpose of preventing any loss of medicament during transportation or in order to reduce the moisture contamination of the medicament during the life of the inhaler. Examples of such are disclosed in EP0211595, where the medicament is loaded directly into a blister pack comprising a sheet; which may be laminated, of foil or plastics material which acts as a carrier and which is provided with a number of breakable or openable containers called "blisters" incorporating a sheet secured on a first sheet forming a cover or lid. A plunger can then be carried by the lid and arranged to

penetrate a container when the lid is moved to its open position. A device disclosed in WO97/25086, comprises a spider having pads, resiliently urged into contact with the pockets of the device, said pads being raised away from the pocket by rotation of the spider prior to the use of the inhaler.

A device disclosed in US5,860,419 comprises medicament metered into blisters. The foil seal is peeled back to expose the medicament such that as the blister approaches the airway it is exposed for use.

However, the problem with these inhalers is that once they are prepared for use, i.e. once the seal of the pocket or "blister" is broken or removed, the medicament is exposed to the atmosphere inside the inhaler. The medicament could be dislodged from the pocket if the inhaler is shaken, dropped, or the user exhales into the device.

Similar problems exist with reservoir inhalers where the dose is metered in use. Examples of reservoir devices include that known as Turbohaler as described in EP0237507 and EP0069715, and the device described in WO97/20589.

Thus according to the present invention there is provided a dose protector for use in an inhaler comprising a housing defining an airway; a dose of medicament optionally retained in a dose container; and covering means for said dose wherein covering means for the dose only opens in response to airflow though and/or pressure drop across the airway in a first direction but not in a second, opposite direction.

Amongst the advantages of the present invention in one or more of its embodiments are included that it provides a reduction in moisture contamination of the medicament, particulate contamination of the dose, loss of the dose if the

device is inverted, dropped or shaken, until the point of inhalation by the patient. Air exhaled into the device by the patient does not come into contact with the medicament, thereby reducing contamination of the medicament by moisture or particulates, or the medicament being dislodged from the pocket by the patient exhaling into the device.

It follows that the advantages of the present invention include that it also ensures that the full dose metered is available to the patient in that part of the dose is prevented from being lost such as, for example being lost within the device, if the complete dose is not taken in the first inhalation, as may be the case with the elderly and children.

Preferably the covering means is only open in the presence of airflow through and/or pressure drop across the airway in a first direction after which it returns to its resting position.

The airflow through and/or pressure drop across the airway in the first direction will generally be caused by patient inhalation.

In one embodiment the covering means is preferably in biased contact with the dose or container retaining the dose. Alternatively the covering means senses airflow through and/or pressure drop across the airway and responds thereto. Thus the covering means responds to airflow through and/or pressure drop across the airway in a first direction by opening.

The means for sensing the airflow though and/or pressure change across the airway and/or the means of responding thereto (i.e. opening said covering means and/or covering the dose more effectively) may incorporate electronic

means. Alternatively it may incorporate mechanical or electromechanical means.

When airflow through and/or pressure drop across the airway is in a second direction the covering means preferably responds by more effectively protecting the dose. For example it may more effectively protect the dose by being urged into closer contact with the dose or container retaining the dose.

The airflow through and/or pressure change in the second direction may generally be caused by the patient exhaling into the device.

The covering means may comprise one or more poppet valves, diaphragm valves, rotary valves, reciprocating valves, sealing flaps or a combination thereof.

There are various ways in which a dose can be metered. In one manner the metering occurs during the manufacturing process of the device ("pre-metered") and the metered dose is retained or located in discrete units. Alternatively the device contains a reservoir containing medicament and the dose is metered in use.

Metering may be based on volume of medicament or surface area.

For metering based on volume the dose may be metered in use or pre-metered into a container of the required volume. More specifically the container may be a pocket wherein the dose is retained after it has been metered. The pocket may also form a throughhole during operation of the device.

For metering based on surface area the dose may be retained on a tape. The covering means may then sit directly on the said dose.

In the dose protector the dose or container retaining the dose may have a surrounding rim. The rim around the dose, container retaining the dose or pocket is not specifically to retain the dose but preferably acts to create a better contact with the said covering means.

Especially preferred is a dose protector for use in an inhaler comprising a housing defining an airway; a pocket suitable for containing a dose of medicament; and at least one sealing flap in biased contact with said pocket and providing a cover for the pocket; wherein the contact between the at least one sealing flap and the pocket is broken by airflow through the airway in a first direction but not in a second opposite direction

Preferably, the sealing flap is spaced away from the pocket by the airflow from the pocket once the contact with the pocket is broken.

A further embodiment of the invention is a dose protector additionally comprising a closure mechanism wherein the at least one sealing flap is held in contact with the pocket by a closure means which prevents the contact between the at least one sealing flap and the pocket being broken by airflow through the airway in any direction. This can create a seal as the closure mechanism may correspond to and complement the shape of the rim. This provides an additional safety feature, decreasing the risk that a child could inhale the medicament accidentally. The movement of the closure mechanism could potentially be combined with the opening of the air inlet. The closure means applies a constant direct pressure on to the sealing flap thereby providing a seal with a long shelf life.

Preferably the pocket has a surrounding rim, which forms the contact point between the pocket and the sealing flap thereby providing a low contact area between the flap and the pocket.

Preferably the sealing flap is made of a flexible, resilient material with a memory, preferably a 3 year memory more preferably a greater than 3 year memory, i.e. the sealing flap stays resilient, biased against the pocket and flexible.

Preferably the sealing flap vibrates in the airflow once the contact with the pocket is broken. This has the effect of increasing the fine particle mass. Features which may influence the ability of the sealing flap are the flexibility of the material, preferably the sealing flap is made of highly flexible material for example a thermoset rubber, to allow the vibration to occur as the pressure changes in the device; the resilience of the sealing flap, if the resilience is too high the sealing flap may not open, if too low the sealing flap may not close therefore vibrations would not occur.

Preferably the sealing flap is of equivalent or slightly reduced width relative to the distance between the inside walls of the housing at the base of the walls of the housing where the sealing flap is in contact with the pocket. Preferably the distance between the inside walls of the housing increases as the distance away from the pocket increases preventing the sealing flap being hampered in its movement as it vibrates.

It will be appreciated that the vibrations of the sealing flap can be affected by the length of the sealing flap and its anchor position on the housing relative to the position of the pocket. The height of the airway may also effect the vibration of the sealing flap by influencing the curve of the sealing flap. The curve of the

sealing flap can be affected by having a locally thinned area on the sealing flap which acts as a hinge, instead of or as well as being made of a highly flexible material.

The covering means is preferably spaced away from the dose or container retaining the dose to coincide with the airflow through and/or pressure drop across the airway once the contact with the dose or container retaining the dose is broken.

In alternative embodiments of the invention the covering means may vibrate in the airflow through and/or pressure drop across the airway in the first direction.

The housing preferably contains a valve flap such that when the airflow is in a second opposite direction, the airflow exits the housing by means of the valve flap. This arrangement allows the airflow to escape from the housing, to prevent build up of pressure.

The said covering means preferably protects the dose from the patient exhaling into the device, moisture contamination, particulate contamination, loss of the dose (e.g. in the device) or a combination thereof.

Preferably the dose protector additionally comprises a fixed seal. This provides a further means by which to prevent loss of drug that can occur in transportation. It also can aid in reducing moisture contamination of the medicament during storage and transportation of the device. This seal (e.g. a pocket seal) will need to be removed before the patient uses the device, but protection of the dose after removal of the pocket seal will still be maintained by the covering means (e.g. sealing flap).

Another aspect of the invention is a dose protector in combination with a dose of medicament.

A second aspect of the invention is an inhaler comprising a body, a mouthpiece and a dose protector according to the invention.

Preferably the dose protector is for use in a dry powder inhaler. For example it may be a reservoir multidose dry powder inhaler, a pre-metered multidose dry powder inhaler or a unit dose dry powder inhaler.

Preferably in the inhaler the dose protector comprises at least one sealing flap in biased contact with a pocket, suitable for containing a dose of medicament, providing a cover for the pocket, the contact between the at least one sealing flap and the pocket being broken by airflow towards the mouthpiece.

Even more preferably the dose protector comprises least one sealing flap in biased contact with a pocket, suitable for containing a dose of medicament, providing a cover for the pocket, the contact between the at least one sealing flap and the pocket not being broken by airflow from the mouthpiece through the body.

Another aspect of the invention is an inhaler in combination with at least one dose of medicament.

Another aspect of the invention is the use of an inhaler for the administration of medicament.

Preferred embodiments of the inhalation device according to the present invention will now be described with reference to the accompanying drawings in which:

Fig. 1a is a sectional side view of a dose protector according to the present invention wherein the sealing flap is at rest.

Fig. 1b is a sectional side view of a dose protector according to the present invention wherein the airflow is in the direction to activate the sealing flap.

Fig. 2a is a sectional side view of a device as shown in Fig 1a and Fig 1b, wherein the valve flap is at rest.

Fig. 2b is a sectional side view of a device as shown in Fig 1a and Fig 1b, wherein the valve is open.

Fig. 2c is a sectional side view of a device as shown in Fig 1a and Fig 1b wherein the airflow is in the direction to activate the sealing flap.

Fig. 3a is a sectional side view of a device as shown in Fig 1a and Fig 1b, wherein the pocket has geometry particularly suitable for a metered dose inhaler.

Fig. 3b is a sectional side view of a device as shown in Fig 1a and Fig 1b, wherein the airflow is in the direction to activate the sealing flap.

Fig. 4a is a dose protector with closure mechanism in the closed position.

Fig. 4b is a dose protector with the closure mechanism in the open position.

Fig. 5 is a sectional side view of a device as shown in Fig 1a and Fig 1, with a pocket seal.

Fig. 6 is a sectional side view of a unit dose powder inhaler having a dose protector as shown in Fig 1a and Fig 1b, where the sealing flap is at rest.

Fig. 7 is a perspective view of a unit dose inhaler having a dose protector shown in Fig 1a and Fig1b at rest.

Fig. 8 is a perspective view of a moulding for a unit dose inhaler similar to that shown in Fig. 6.

Fig 9 is a different perspective view of a unit dose inhaler similar to that shown in Fig. 6

Figures 1a and 1b show a first dose protector comprising a sealing flap 10 and a pocket 20 suitable for containing a dose of medicament. The sealing flap 10 is resiliently biased into contact with the edge of the pocket 30 to reduce moisture contamination and loss of medicament during transportation. The sealing flap is fixedly attached to the body of the housing 40. When air flows towards the sealing flap as shown in Fig. 1b, such airflow being created by inhalation by the patient, the contact between flap 10 and the edge of the pocket 30 will break, and medicament is entrained in the airflow.

The sealing flap can vibrate to increase the fine particle mass of the medicament.

Fig. 1a shows that when the air flows towards the sealing flap 10 in the direction shown, the contact between the sealing flap 10 and the edge of the pocket 30 is

not broken, thereby maintaining the protection of the dose from moisture and particulate contamination. Such airflow would usually be created by exhalation.

Figures 2a, 2b and 2c show a second aspect of the invention having a hole 150 in the housing 140 so when the airflow is due to exhalation by the patient the valve flap 160 opens to let the moist air out. However when the airflow is in the opposite direction the contact between the sealing flap 110 and the edge of the pocket 130 is broken.

Figures 3a and 3b show a further dose protector according to the invention having a sealing flap 210 and a pocket 220 having geometry particularly suitable for a metered dose inhaler.

Figures 4a and 4b show the closure mechanism in an open and closed position. The locking means having slidable movement relative to the pocket where in the closed position the legs 380 sit over the edge of the pocket 330 trapping the sealing flap 310 between the legs and the edge of the pocket 330 preventing movement of the sealing flap 310. To open the device, the closure mechanism is slid relative to the pocket so that the legs 380 are not over the rim of the pocket and the sealing flap is not trapped, but free to move when airflow is in the correct direction.

Fig. 5 shows a dose protector according to the invention additionally having a pocket seal 490, which may be laminated, of foil or plastics material, which is removed to ready the device for use by the patient.

Fig. 6 shows a unit dose powder inhaler having a body 506 a mouthpiece 505 air inlet holes 507 a sealing flap 510 and a pocket 520. When the patient inhales through the mouthpiece 505 air flows into the device through the air inlet

holes 507 and the contact between the sealing flap 510 and the pocket 520 is broken. The medicament present in the pocket 520 is entrained in the airflow and carried through the device to be administered to the patient.

Fig 7 shows a unit dose inhaler wherein pocket 720 containing medicament is covered by sealing flap 710.

Fig 8 shows a one-piece moulding for a unit dose powder inhaler similar to that illustrated in Fig. 6 wherein 820 is the pocket and 810 is a sealing flap which bends into position when one half of the moulding is folded over and closed to form the finished device.

Mouldings as shown in Fig. 8 may be formed in arrays which allows for convenient filling of the pockets with medicament in an automated process.

Fig. 9 shows a unit dose inhaler with a pocket containing medicament 920 and a flexible resilient sealing flap 910 located fixedly through a tight fitting slot 970 in the top of the device. The material of the sealing flap is thinned at the slot to improve its positioning.

Throughout the specification and the claims which follow, unless the context requires otherwise, the word 'comprise', and variations such as 'comprises' and 'comprising', will be understood to imply the inclusion of a stated integer or step or group of integers but not to the exclusion of any other integer or step or group of integers or steps.